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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,526	07/24/2003	Morton M. Mower	06809-0031-00000	8161
22852	7590	05/02/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			PATEL, NATASHA	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/625,526	<b>Applicant(s)</b> MOWER, MORTON M.	
	<b>Examiner</b> Natasha N. Patel	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                                             |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/04 &amp; 4/11/06</u> . | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species:

Species A: Dual chamber cardiac pacemaker.

Species B: Bi-chamber cardiac pacemaker.

2. The species are independent or distinct because a dual chamber cardiac pacemaker has different effects on the heart compared to a bi-chamber cardiac pacemaker.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Art Unit: 3766

6. During a telephone conversation with David Longo on 4/14/06 a provisional election was made without traverse to prosecute the invention of the dual-chamber pacemaker, claims 1-16 and 24-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-23 and 28-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 10, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (US Patent 6,937,895).

9. Regarding Claims 1, Lu discloses a multi-chamber cardiac pacemaker (10), comprising: a first electrode electrically coupled to an atrial chamber (tip electrode 22); a second electrode electrically coupled to a ventricular chamber (tip electrode 32); a signal generator to generate a sequential pair of pacing pulses (see col. 7, lines 36-40); a first lead (right atrial lead 20) coupled to the signal generator and to the first electrode; a second lead (right ventricular lead 30) coupled to the signal generator and to the second electrode; a distributor circuit (switch 74), connected between the first lead and the signal generator and between the second lead and the signal generator (see Figure

Art Unit: 3766

2), to receive the pair of pacing pulses, distribute a first pacing pulse from the pair at a first amplitude to the first lead, and distribute a second pacing pulse from the pair at a second amplitude to the second lead after a delay period (see Table 1, col. 11). The examiner considers that a multi-chamber pacemaker is capable of pacing two chambers so a multi-chamber is inherently a dual chamber pacemaker as well. Furthermore, the examiner considers that the switch 74 is equivalent to the distributor circuit because it is in fact in control of determining which chamber the pulse is directed towards. The applicant's claim language does not come under the purview of §112, 6<sup>th</sup> paragraph, so any circuit that distributes will be considered a distributor circuit. Lu discloses that the distributor circuit receives a pair of pulses, one from the atrial pulse generator 70 and one from the ventricular pulse generator 72 (see Figure 2). The examiner considers that the two pulses are delivered to two different leads because there is a separate lead shown for each of the two chambers (see 20 and 30, Figure 1) and if each chamber has its own lead, then both leads would have to carry a pulse if both chambers are to be stimulated. Furthermore, the examiner considers a pulse pair to be a related set of pulses such as a triggering stimulation and a concomitant delayed stimulation pulse like the ones shown in lines 1, 2, 5, 6, etc. in Table 1. Also, it is inherent that each pulse will possess some amplitude. If there is no amplitude, there is no pulse delivered. Finally, since stimulation to the RV is administered after stimulation to the RA, a delay period exists, as shown in Table 1.

10. Regarding Claim 2, Lu discloses that the signal generator generates a sequential pair of electrical pacing pulses (see Claim 28, 4<sup>th</sup> part). The examiner considers that

since there is a delay between the two stimulation pulses, they are sequential because the existence of a delay means the two pulses are not delivered at the same time. Lu does not disclose that the two pulses are of the same amplitude. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention to make the pulses of either the same amplitude or different amplitudes. The applicant does not disclose that making the pulses of equal amplitude provides an advantage, is used for a particular purpose, or solves a stated problem. In fact, the applicant says that either choice would allow the invention to perform equally well (see Spec. par. 64, last sentence). Furthermore, the relative amplitude of the pulses depends upon the electrical properties of the tissue and location of the stimulation. Thus, it would have been obvious to implement same amplitude pulses in Lu's invention because such a modification would have been considered a mere design consideration, which fails to patentably distinguish over the prior art.

11. Regarding Claim 3, Lu discloses an atrial circuit (atrial sensing circuit 82), connected to the first electrode, to sense depolarization in the atrial chamber; and a ventricular circuit (ventricular sensing circuit 84), connected to the second electrode, to sense depolarization in the ventricular chamber (see col. 8, lines 26-45).

12. Regarding Claim 4, Lu discloses that the signal generator generates the sequential pair of electrical pacing pulses in response to a signal from the atrial circuit (see col. 8, lines 15-20).

Art Unit: 3766

13. Regarding Claims 10 and 26, Lu discloses that the distributor circuit further comprises a switch to intermittently couple the signal generator to the first and second leads (see col. 7, lines 31-36).

14. Regarding Claim 24, Lu discloses a multi-chamber cardiac pacemaker apparatus (10), comprising: first means for electrically coupling the apparatus to an atrial chamber (tip electrode 22); second means for electrically coupling the apparatus to a ventricular chamber (tip electrode 32); signal generator means for generating a sequential pair of pacing pulses (see col. 7, lines 36-40); and distribution means (switch 74) for distributing a first pacing pulse from the pair at a first amplitude to the first means, and for distributing a second pacing pulse from the pair at a second amplitude to the second means after a delay period. Comments parallel to those made above in the rejection of Claim 1 apply here as well. The examiner considers that the distribution means is equivalent to switch 74 because the distribution means, as disclosed by the applicant, is basically a switch with additional electronic circuitry that would have been obvious to include as explained in the rejection of Claims 5-16.

15. Regarding Claim 27, Lu discloses a plurality of leads (leads 20 and 30) coupling the signal generator to the first and second means (tip electrodes 22 and 32).

16. Claims 5, 7, 9, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (US Patent 6,937,895) in view of Pohndorf et al. (US Patent 4,628,934).

17. Regarding Claims 5 and 9, Lu does not disclose having a flip-flop. Pohndorf discloses a similar distributor circuit (switching/selection circuit 348, Figure 8)

Art Unit: 3766

comprising a bistable flip-flop connected between the signal generator and the first lead (see col. 10, lines 18-21). A flip-flop is often used as a switch among feedthroughs responsible for distributing specific signals for specific periods of time to the feedthroughs and eventually the pacing leads (see col. 12, lines 28-31). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Pohndorf's flip-flops because the flip-flops allow for signals to be sent down multiple pathways, enabling the stimulation of multiple chambers as disclosed by Lu.

18. Regarding Claim 7, Lu does not disclose a zener diode. Pohndorf discloses a zener diode configured to adjust the amplitude of at least one of the sequential pair of pacing pulses (see col. 8, lines 5-11). The examiner considers that protecting against damaging high voltages results in the adjustment of the amplitude of a pulse if that pulse is nearing a dangerous high voltage. Pohndorf does not disclose that the zener diode is connected to the flip-flop within the distributor circuit. However, it would have been obvious to one of ordinary skill in the art to put the zener diode anywhere between the pulse generator and the lead so that the amplitude could be adjusted before the pulse reached the chamber being stimulated. Furthermore, the applicant does not provide criticality to the placement of the zener diode within the distributor circuit or connecting it to the flip-flop. Shifting the zener diode from outside of the distributor circuit, as disclosed by Pohndorf (see col. 8, lines 59-64), to the inside of the distributor circuit, as claimed by the applicant, does not modify the operation of the device (*In re Japikse* 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to connect the zener diode

Art Unit: 3766

to the flip-flop since the Schmitt trigger is connected to the flip-flop so that both amplitude and time can be adjusted from a central location within the distributor circuit.

19. Regarding Claim 13, Lu discloses a delay circuit (timing control 79) to delay at least one of the sequential pair of pacing pulses (see col. 7, lines 45-52). Lu does not disclose that the delay circuit is coupled to the distributor circuit (switch 74). Pohndorf discloses a similar delay circuit (see col. 7, lines 1-12) that is coupled to the distributor circuit (switching/selection circuit). The examiner considers the additional programming circuitry of Pohndorf's invention is equivalent to a delay circuit because it may include a switch and the time it takes to make the switch from stimulating one lead to stimulating another lead is a delay.

20. Regarding Claim 14, Lu does not disclose an inductor. Pohndorf discloses that the delay circuit comprises at least one inductor (see col. 7, lines 4-9). The examiner considers that an inductive coupling means is equivalent to an inductor because both are capable of opposing changes in current.

21. Regarding Claim 15, Lu does not disclose a capacitor. Pohndorf discloses at least one capacitor (see col. 7, lines 28-33). Although Pohndorf does not disclose that the capacitor is in the delay circuit, it would have been obvious to one of ordinary skill in the art at the time of the invention to put the capacitor in the delay circuit because of the capacitor's ability to achieve desired timing functions through its charging schemes. Capacitors are well known and commonly used in pacemaker circuitry for timing delays. Furthermore, the applicant does not disclose any criticality to having the capacitor in the delay circuit over having the capacitor in any other location. Shifting the capacitor to the

Art Unit: 3766

inside of the delay circuit, as claimed by the applicant, does not modify the operation of the device (*In re Japikse* 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the capacitor in the delay circuit since the delay circuit concerns timing delays between stimulation pulses.

22. Regarding Claim 16, Lu does not disclose a zener diode. Pohndorf discloses at least one Zener diode configured to distribute the sequential pair of pacing pulses to the first and second leads (see Claim 29 and col. 4, lines 55-59). Zener diodes are common in the pacemaker art as they provide defibrillation protection (see col. 4, lines 55-59). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the zener diodes disclosed by Pohndorf to provide protection to the pacemaker disclosed by Lu, especially since Lu's pacemaker is also used for defibrillation.

23. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (US Patent 6,937,895) and Pohndorf et al. (US Patent 4,628,934) in view of Vollmann et al. (US Patent 4,561,442).

24. Regarding Claim 6, Lu does not disclose having an adjustable Schmidt trigger. Vollmann discloses a similar distributor circuit (microprocessor clock 60) comprising an adjustable schmidt trigger (Schmitt trigger 98) connected to the flip-flop (flip-flop 96) and configured to adjust the timing of at least one pulse of the sequential pair of pacing pulses (see col. 3, lines 46-61). The examiner considers if the Schmitt trigger is configured to turn on the microprocessor clock at a specific point in time to issue a

Art Unit: 3766

pulse, then essentially the trigger is in charge of the timing of the pulse because a pulse will not be issued until the microprocessor clock is turned on. Since Schmitt triggers are used for their oscillating capabilities (see col. 12, lines 10-12), it would have been obvious to implement such an electrical component into Lu's pacemaker circuitry by anyone looking to vary the signals being sent out to the different chambers of the heart. Thus, one of ordinary skill in the art at the time of the invention would have found it obvious to implement the Schmitt trigger into the pacemaker circuitry disclosed by Lu because it allows for more stimulation options.

25. Claims 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (US Patent 6,937,895) and Pohndorf et al. (US Patent 4,628,934) in view of Vollmann et al. (US Patent 4,561,442) in further view of Duggan (US Patent 5,318,593).

26. Regarding Claims 8 and 25, Lu does not disclose a clamping circuit. Duggan discloses similar pacemaker circuitry comprising an adjustable clamping circuit (see col. 16, lines 12-20). Duggan also discloses adjusting the amplitude of at least one of the sequential pair of pacing pulses (see col. 5, lines 17-22). The examiner considers that if a clamping circuit can be used to adjust pulse width, then it can also be used to adjust one of the other signal parameters listed, such as amplitude. This is especially reasonable because the clamping circuit clamps the amplifier (see col. 16, lines 12-14), which is in charge of determining the signal amplitudes. Duggan does not disclose that the clamping circuit is connected to the flip flop within the distributor circuit. Once again, it would have been obvious to one of ordinary skill in the art to put the clamping circuit anywhere between the pulse generator and the lead so that the amplitude could be

Art Unit: 3766

adjusted before the pulse reached the chamber being stimulated. Furthermore, the applicant does not provide criticality to the placement of the clamping circuit within the distributor circuit or connecting it to the flip-flop. Shifting the clamping circuit to the inside of the distributor circuit, as claimed by the applicant, does not modify the operation of the device (*In re Japikse* 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to connect the clamping circuit to the flip-flop if the Schmitt trigger and the zener diode are connected to the flip-flop so that both amplitude and time can be adjusted from a central location within the distributor circuit.

27. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (US Patent 6,937,895) in view of Duggan (US Patent 5,318,593).

28. Regarding Claims 11 and 12, Lu does not disclose a resistor. Duggan discloses similar pacemaker circuitry comprising a resistor, connected between the switch (130b) and the first lead (17), to provide the first pacing pulse at the first amplitude. Duggan also discloses another resistor, connected between the switch (130a) and the second lead (19), to provide the second pacing pulse at the second amplitude (see Figure 3B). Since a shunt resistor is merely a parallel resistor, Duggan is disclosing a shunt resistor. The use of the shunt resistor in the voltage divider circuit to provide the necessary amplitude is a standard practice as shown by Duggan. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a shunt resistor to control the amplitude of the signals and essentially vary the stimulation pulses of Lu's invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766